UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

BRIA MILLER and JORDAN JUDT, on behalf of themselves and a class of all others similarly situated, Plaintiffs, v. TARGET CORPORATION, Defendant.	Case No: 0:24-CV-01323-ECT-JFD

MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANT'S MOTION TO DISMISS THE AMENDED COMPLAINT

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Plaintiffs Bria Miller and Jordan Judt bring this putative consumer fraud class action for economic harm against Defendant Target Corporation ("Target"). Plaintiffs allege Target sold benzoyl peroxide acne drugs that failed to warn consumers they contained or would "degrade over time to contain" benzene. The Complaint relies wholly on a recent study and subsequent Citizen Petition to the Food and Drug Administration ("FDA") by Valisure, LLC, which claims that Valisure detected benzene in a sampling of benzoyl peroxide ("BPO") acne products that were subjected to extreme temperatures for extended periods of time.

But the Valisure study provides no basis for Plaintiffs' claims. As Valisure concedes in its March 5, 2024 Citizen Petition, Valisure did not test every BPO acne product. (Ex. 1 (Citizen Petition)[1] at 11 ("many brands and formulations are not included in Valisure's

[1] Pursuant to Federal Rule of Evidence 201, the incorporation by reference doctrine, and this Court's inherent authority, Target respectfully requests that the Court take judicial notice of the Valisure Citizen Petition on Benzene in Benzoyl Peroxide Drug Products, found at https://www.regulations.gov/document/FDA-2024-P-1130-0001, with FDA Document ID number FDA-2024-P-1130-0001. The Court may take judicial notice of Exhibit 1, which is the full text of a publicly-available document referenced by Plaintiffs in the Complaint, because it is referenced in Plaintiffs' Amended Complaint and is "embraced by" and central to Plaintiffs' claims. *See, e.g.*, *Zean v. Fairview Health Servs.*, 858 F.3d 520, 527 (8th Cir. 2017); *Trustees of Welfare & Pension Funds of Loc. 464A - Pension Fund v. Medtronic PLC*, No. 22-cv-2197 (KMM/JFD), 2024 WL 1332262, at *28, n.35 (D. Minn. Mar. 28, 2024); *United Healthcare Servs. v. AmerisourceBergen Corp.*, 23-cv-2890 (DWF/ECW), at *5 n.3 (D. Minn. Apr. 24, 2024) ("The Court takes judicial notice of . . . materials posted on government websites."). Target's request is limited to the Court

analysis")). Valisure also did not detect benzene in every BPO acne product it tested, even after subjecting them to prolonged extreme temperatures. The Valisure study, at best, indicates that some BPO acne drugs can degrade when exposed to high heat for a long time. But Plaintiffs allege no plausible nexus between the products they purchased and those that Valisure later tested, nor that any such exposure or degradation occurred. Since the alleged deception only *assumes* Plaintiffs' products were unsafe, Plaintiffs have failed to allege any injury-in-fact, depriving them of standing to bring their claims—each of which is based on this theory of deception. For the same reasons, Plaintiffs fail to state a claim, particularly any claim of fraud.

Further, Plaintiffs' deception claims are expressly preempted because federal law provides that products are safe if they conform to FDA's monograph for topical over-the-counter ("OTC") BPO acne drugs ("Acne Monograph"). Here, Plaintiffs do not allege the products they purchased at Target ("BPO Products") contravene the Acne Monograph. Rather, Plaintiffs complain their BPO Products were unsafe because they did not deviate from the Acne Monograph by adding a benzene warning or otherwise listing benzene, a possible contaminant, as an intentional ingredient. Such deviation from the requirements

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taking notice of the fact of the Valisure Citizen Petition and its contents, but not for the truth of any statements contained therein. In the limited circumstances presented by Target's Motion, the fact that the statements were made is relevant and indisputable. Plaintiffs do not dispute the authenticity of this document.

of the Federal Food, Drug, and Cosmetic Act ("FDCA") would render the products misbranded and illegal to sell. Plaintiffs' claims thus seek to create an impermissible conflict between federal and state law.

To the extent Plaintiffs seek to impose on Target an obligation to make specific claims about the BPO Products and their safety grounded in FDCA-imposed safety standards or protocols, those claims are impliedly preempted. The obligations for testing, quality standards, and recalls do not exist without the FDCA. Plaintiffs' claims fail whether they challenge conduct that conforms to the FDCA, *i.e.*, the warnings imposed under the Acne Monograph, or conduct that purportedly violates FDCA requirements to test, meet specifications, or recall.

Alternatively, FDA has primary jurisdiction to determine drugs' safety and the warnings they bear. Valisure has already initiated FDA's Citizen Petition process. (Compl. ¶ 4); *see also* 21 C.F.R. § 10.30. If the Court does not find Plaintiffs' claims preempted, it nevertheless should dismiss or stay the action so FDA may assess the safety and adequacy of warnings of OTC BPO acne drugs.

As further detailed below, Plaintiffs' Complaint is defective for myriad reasons, which cannot be cured by amendment.

I. FACTUAL BACKGROUND

This case is not a typical deceptive advertising action about the advertised benefits of a product. It is really about whether the BPO Products are actually safe or whether they

might be contaminated with benzene and therefore unsafe. (*See* Compl., ¶¶ 1, 10). But that determination properly remains with the FDA.

A. The FDA-Regulated Drug Monograph System.

FDA regulates OTC benzoyl peroxide acne medications like the BPO Products via its drug monograph system, which evaluates their safety. *See* 21 C.F.R. § 333.301 *et al*.; *Stephens v. Target Corp.*, 22-CV-1576 (PJS/DTS), 2023 WL 6218060, at *3 (D. Minn. Sep. 25, 2023). In drafting monographs, FDA established OTC drug categories and assigned an advisory review panel ("Committee") of qualified experts tasked with evaluating the safety and effectiveness of OTC drugs, reviewing drugs' labeling, and advising the FDA Commissioner on the promulgation of monographs by establishing conditions under which OTC drugs listed within each monograph are generally recognized as safe, effective, and not misbranded. 21 C.F.R. §§ 330.5, 330.10(a). The Committee reviews clinical studies, reports of documented side effects, and other pertinent information to make recommendations, engages in a notice and comment period, and publishes a proposed and ultimately final monograph that establishes the conditions under which an OTC drug is safe, effective, and not misbranded. *See id.* § 330.10. This process results in "a detailed regulation — a 'monograph' — for each therapeutic class of OTC drug products. Like a recipe, each monograph sets out the FDA-approved active ingredients … and provides the conditions under which each active ingredient is [generally recognized as safe and effective ("GRAS/E")]." *Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 710 F.3d 71, 75 (2d Cir. 2013), as amended (Mar. 21, 2013). FDA excludes from its

monographs any active ingredients or uses of active ingredients it has determined either not to be GRAS/E or for which there is insufficient data to confirm whether they are GRAS/E. *Id.* Although any interested person may petition for the amendment or repeal of any monograph under FDA's Citizen Petition process, an OTC drug that fails to conform to its applicable monograph is liable to regulatory action. *See* 21 C.F.R. §§ 10.30, 330.10(a)(12), (b) ("Any product which fails to conform to an applicable monograph after its effective date is liable to regulatory action.").

B. Benzoyl Peroxide's Addition to the Acne Monograph after Extensive FDA Review.

Benzoyl peroxide was not an authorized active ingredient in FDA's original 1991 Acne Monograph because, at that time, the Agency was still studying benzoyl peroxide's potential for carcinogenicity. 21 C.F.R. §333.310; Final Rule, 56 FR 41008. Following FDA's proposed monograph status for benzoyl peroxide, the Agency became aware of a study that raised a safety concern regarding benzoyl peroxide's tumor initiation potential. *Id.* For nearly twenty years, benzoyl peroxide topical acne drugs remained on the market under a tentative final monograph for further study. *See* Classification of Benzoyl Peroxide as Safe and Effective and Revision of Labeling to Drug Facts Format; Topical Acne Drug Products for Over-The-Counter Human Use; Final Rule, 75 FR 9767-01. During that time, the Committee recommended that known safety data regarding the tumor promoting potential of benzoyl peroxide should be communicated to consumers. *Id.* at 9768. Because this data was inconclusive, the Committee unanimously agreed that the word "cancer"

should not be included in the labeling. *Id.*

In 2010, FDA issued a final rule that "conclude[d] that benzoyl peroxide, in concentrations of 2.5 to 10 percent, is GRAS/E for the OTC topical treatment of acne." *Id.* This conclusion was based on safety data generated by two long-term studies FDA determined "were well-designed and . . . adequately exclude the possibility that benzoyl peroxide is a carcinogen with a short or long latency period." *Id.* at 9770. According to FDA, "[d]ermal carcinogenicity and photocarcinogenicity studies best represent actual use conditions for benzoyl peroxide. They are the benchmark for determining the carcinogenic potential of a drug. We believe that the negative findings in the carcinogenic and photocarcinogenic studies support a GRASE conclusion for benzoyl peroxide . . ." *Id.* at 9771. The 2010 final rule adding benzoyl peroxide as an authorized active ingredient under the Acne Monograph also included new warnings and directions required specifically for OTC acne drug products containing benzoyl peroxide. *Id.* at 9772; 21 C.F.R. § 333.350(c)(4), (d)(2).

C. Third-Party Valisure's 2023 Testing Of Various BPO Acne Products

All of Plaintiffs' claims are based on Valisure's testing of various BPO acne products and its conclusion that "*all on-market BPO acne formulations* seem to be fundamentally unstable and form unacceptably high levels of benzene under normal use, handling, and storage temperatures." (Compl., ¶ 44 (emphasis added).) Valisure's testing methodology involved subjecting its limited sampling of BPO products, for weeks at a time, to "above-ambient temperatures, specifically, 37°C (98.6°F), 50°C (122°F), and 70°C

(158°F).” (Ex. 1 at 1.) The results of Valisure’s testing are pictured at Figure 4 of the Citizen Petition. (*See also* Compl., ¶ 42.) Valisure tested “specific batches” of various BPO products and, as shown in Figure 4 of the Citizen Petition, the results are labeled “by the BPO percentage they contained, the brand name, the product type and the Universal Product Code (‘UPC’) number.” (*Id*. at 16.) Benzene was not detected in all the BPO acne products Valisure tested, even after being subjected to extreme temperatures for weeks at a time. (*Id*. at 1.) Nonetheless, Valisure called for a recall of ***all*** BPO acne products on the market, based on the alleged risk they “could produce substantial amounts of benzene when stored at above-ambient temperatures ....” (*Id*.)

D. Plaintiffs’ Lawsuit Claims

Although Plaintiffs apparently claim BPO Products generally might be unsafe, they allege no facts ***specific to their BPO Products***. They plead ***nothing*** about testing their individual products, the normal shipping and handling of the BPO Products in 2022, or even the conditions in which they stored or used their BPO Products.

Plaintiffs allege two types of purportedly deceptive conduct by Target. First, Plaintiffs claim Target failed to communicate to make the BPO Products safe:

- Target never listed benzene in the ingredients list on the BPO Products’ labels, or advertising (Compl. ¶¶ 8, 10-13, 49); and
- Target failed to warn the BPO Products had or were *at risk of* benzene contamination (Compl. ¶¶ 8, 98) (emphasis added).

Second, Plaintiffs claim Target failed to take further action regarding the safety of BPO Products:

- The BPO Products were adulterated because Target failed to make or test them in conformity with current good manufacturing practices or quality, safety, and purity specifications (Compl. ¶¶ 4, 50-52, 111); and
- Target failed to recall any BPO Products that may contain benzene (Compl. ¶¶ 4, 29, 52.).

Importantly, Plaintiffs do not allege the BPO Products failed to conform to FDA's Acne Monograph. Rather, they complain Target sold the BPO Products in conformance with the Acne Monograph when Target should have substituted FDA's judgment for its own to warn about the risk of benzene contamination in products made without benzene. As shown below, that cannot be correct and Plaintiffs claims should be dismissed.

II. LEGAL STANDARD

A complaint should be dismissed under Rule 12(b)(6) unless it "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). To survive a motion to dismiss under Rule 12(b)(6), a plaintiff must plead facts showing that his "right to relief [rises] above the speculative level." *Twombly*, 550 U.S. at 555. A plaintiff must show "more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678. Although the Court must accept material factual allegations as true, "[t]hreadbare recitals of the elements of a cause of action, supported by

mere conclusory statements, do not suffice[,]" and pleadings that are "no more than conclusions, are not entitled to the assumption of truth." *Id*. at 678-79 (citing *Twombly*, 550 U.S. at 555).

III. ARGUMENT

A. Plaintiffs Fail to State Any Claim Because They Have Not Plausibly Alleged Their BPO Products Contained Benzene.

It is "well established [in the Eighth Circuit] that purchasers of an allegedly defective product have no legally recognizable claim where the alleged defect has not manifested itself in the product they own." *Thunander v. Uponor, Inc*., 887 F. Supp. 2d 850, 861 (D. Minn. 2012). Plaintiffs allege nothing about testing showing benzene in ***their*** BPO Products. They fail to allege a nexus between any of the products Valisure tested and the BPO Products they purchased. They do not allege they subjected the BPO Products to the "above-ambient" temperatures described in the Citizen Petition. Even if they had, those allegations would still be insufficient to allege their BPO Products contained benzene, since they have also alleged facts showing that not all BPO acne products subjected to high temperatures degrade to benzene. Plaintiffs fail to distinguish their BPO Products from those that were tested and found to be benzene-free.

And, since the wholly speculative presence of benzene underpins the alleged deception—that BPO Products are unsafe—in each of their claims, Plaintiffs have failed to state ***any*** claim. Numerous cases in the Eighth Circuit and across the country agree. For example, in *Thunander v. Uponor*, the plaintiffs brought claims under Minnesota consumer protection laws alleging their homes contained defective plumbing. 887 F. Supp. 2d 850

(D. Minn. 2012). In particular, they claimed they received a different pipe formulation than they purchased based on a memo from the defendant company that purportedly detailed a "scheme of fraud and deceit." *Id.* at 857. The court granted the defendant's motion to dismiss because it found plaintiffs had not adequately pleaded a defect. *Id.* at 862. The court noted that in the Eighth Circuit, "[c]ourts have been particularly vigilant in requiring allegations of injury or damages in products liability cases" and "purchasers of an allegedly defective product have no legally recognizable claim where the alleged defect has not manifested itself in the product they own." *Id.* at 861 (citing *Briehl v. General Motors Corp*., 172 F.3d 623, 627 (8th Cir. 1999) and *O'Neil v. Simplicity, Inc*., 574 F.3d 501, 503 (8th Cir. 2009)). As the court explained, the plaintiffs simply alleged their piping was at risk for a manufacturing defect, but did not perform any testing of their plumbing and therefore were "unable to allege sufficient facts to plausibly establish that their pipes are in fact defective or nonmerchantable." *Id.* at 862. The court concluded, "[h]ad the [] Complaint alleged that they had tested their pipes and found that their plumbing system contained the defective pipe referenced in the [] Memo, they might have pled enough facts to state a claim to relief that is plausible on its face." *Id*.

Numerous other cases from the Eighth Circuit as well as cases across the country have reached the same conclusion, including related to alleged testing by Valisure. *See, e.g*., *In re Polaris Mktg., Sales Practices, & Prods. Liab. Litig*., 9 F.4th 793, 797 (8th Cir. 2021) (dismissing claims for alleging the existence of a defect but failing to allege actual injury, finding that "the purchasers do not allege that any manifest defect is present in their

vehicles. They allege that excessive heat ***can*** cause microscopic degradation in plastic and metal . . . But they do not allege that their vehicles exhibit any manifest-but-invisible degradation." (emphasis in original)); *Bowen v. Energizer Holdings, Inc.*, 2022 WL 18142508, at *4 (C.D. Cal. Aug. 29, 2022) ("Plaintiffs' claim is based on the ***hypothetical*** possibility that the products she purchased ***may*** have contained benzene – not that she purchased a product that demonstrably did contain benzene, such as from a batch identified by Valisure." (emphasis in original)); *Clinger v. Edgewell Personal Care Brands, LLC*, 2023 WL 2477499, at *7 (D. Conn. Mar. 13, 2023) ("It would be speculative—rather than plausible—to conclude that benzene was present in Banana Boat product lines for which there are no positive test results for the presence of benzene."); *Rooney v. Procter & Gamble Co.*, 2022 WL 17092124, at *3 (E.D. La. Nov. 21, 2022) (dismissing a complaint alleging the presence of benzene in antiperspirant based on a Valisure study, reasoning that "the Valisure citizen's petition does not state that every single sample of Secret that Valisure tested contained benzene."). Accordingly, because Plaintiffs have not adequately alleged the BPO Products they purchased contain benzene, their claims must be dismissed.

B. Plaintiffs Lack Standing to Assert Claims Individually Or On Behalf Of A Class.

1. Plaintiffs Have Not Alleged An Injury-In-Fact And Lack Article III Standing.

Because Plaintiffs state no facts to plausibly allege their BPO Products contained benzene and were actually unsafe, they lack an injury-in-fact and Article III standing. *See TransUnion LLC v. Ramirez*, 141 S. Ct. 2190 (2021) ("Article III standing requires a

concrete injury even in the context of a statutory violation." (quoting *Spokeo, Inc. v. Robins*, 578 U.S. 330, 341 (2016)). To demonstrate the "personal stake" necessary for Article III standing, "[P]laintiffs must be able to sufficiently answer the question: 'What's it to you?'" *Id.*; *see also Bassett v. Credit Bureau Servs., Inc*., 60 F.4th 1132, 1135 (8th Cir. 2023) (citing *TransUnion* and reversing and remanding putative class action where the court found the plaintiff lacked standing because there was no concrete injury-in-fact).

Plaintiffs allege no nexus between the BPO Products and those Valisure tested. Valisure's Citizen Petition demanding a recall of "all products containing BPO" (Compl., ¶ 4) fails to establish the BPO Products are unsafe and Plaintiffs were harmed by them. *See Cascio v. Johnson & Johnson*, 2024 WL 693489, *2 (N.D. Ga. Feb. 20, 2024) (explaining that a "recall notice alone cannot support a plausible inference that the sunscreen [plaintiff] used contained benzene[,]" reasoning that "'[a] recall will often be overinclusive' and that 'the mere existence of a recall does not prove that any individual's [product] actually contained a nonconformity.'" (quoting *Burbank v. BMW of N. Am., LLC*, 2022 WL 833608, at *9 (D.N.J. Mar. 21, 2022)); s*ee also Thacker ex rel. Thacker v. Kroger Co*., 155 F. App'x 946, 948 (8th Cir. 2005) (unpublished) (recognizing a recall was mostly cautionary and denying liability where plaintiffs could not show their product was defective).

Plaintiff cannot rely on the hypothetical, but unrealized *risk* of benzene exposure to state an injury. (*See* Ex. 1, (Citizen Petition) at 1 (emphasis added) ("BPO products ***could*** produce substantial amounts of benzene when stored at above-ambient temperatures . . . ."); *cf. Bowen v. Energizer Holdings, Inc*., 2022 WL 18142508, at *6 (C.D. Cal. Aug. 29,

2022) (explaining that the allegation that "benzene at 0.1 ppm in a sunscreen *could* expose people to excessively high nanogram amounts of benzene" was insufficient to state a claim because it "creates only a speculative risk of harm . . . ." (emphasis in original)).) Thus, dismissal is warranted. *See, e.g.*, *Johannessohn v. Polaris Industries, Inc*., 9 F.4th 981, 987-88 (8th Cir. 2022) (finding plaintiffs had no standing because they did not demonstrate a sufficient particularized and actual injury where they purchased ATVs that did not start on fire in a class action involving claims under various state consumer protection laws based on an alleged design defect for excessive heat in ATVs); *Thunander*, 887 F. Supp. 2d at 865 (finding plaintiffs "failed to allege enough facts to sustain a plausible allegation of injury" and therefore lacked standing because they did not test the product at issue to determine whether it exhibited the alleged defect); *Wallace v. ConAgra Foods, Inc*., 747 F.3d 1025, 1030 (8th Cir. 2014) ("Without any particularized reason to think the consumers' own packages of Hebrew National beef actually exhibited the alleged non-kosher defect, the consumers lack Article III standing to sue ConAgra."); *Schloegel v. Edgewell Pers. Care Co*., 2022 WL 808694, at *2 (W.D. Mo. Mar. 16, 2022) (dismissing for lack of standing because the plaintiff failed to allege that she actually purchased Banana Boat sunscreen containing benzene, therefore lacking any particularized injury); *Pels v. Keurig Dr. Pepper, Inc.*, 2019 WL 5813422, at *5 (N.D. Cal. Nov. 7, 2019) (dismissing for lack of standing where plaintiff did not allege that "the water *he* purchased contained violative arsenic levels"); *Doss v. Gen. Mills, Inc.*, 2019 WL 7946028, *2-3 (S.D. Fla. June 14, 2019), *aff'd*, 816 F. App'x 312 (11th Cir. 2020) (dismissing for failure to plead injury

in fact where plaintiff failed to "allege that the Cheerios she herself bought actually contain any glyphosate—just that some Cheerios that have been tested do").

2. Plaintiffs Lack Standing To Assert Claims Relating To Products They Did Not Purchase.

Plaintiffs lack standing to represent a National Class of consumers who bought "BPO Products" they never purchased (Compl., ¶¶ 1, 53.). *See, e.g.*, *In re Gen. Mills Glyphosate Litig.*, No. 16-cv-2869 (MJD/BRT), 2017 WL 2983877, at *3 (D. Minn. July 12, 2017) (dismissing the plaintiffs' claims based on 20 varieties of Nature Valley Products for lack of standing because the plaintiffs did not purchase those varieties); *Chin v. Gen. Mills, Inc.*, No. 12-cv-2150 (MJD/TNL), 2013 WL 2420455, at *3 (D. Minn. June 3, 2013) (same, noting "that other courts routinely dismiss claims in consumer class actions that attempt to seek relief relating to products that the named plaintiffs have not purchased"); *Kelly v. Cape Cod Potato Chip Co.*, 81 F. Supp. 3d 754, 763 (W.D. Mo. Jan. 27, 2015) (concluding that the plaintiff lacked standing to assert claims alleging misrepresentation of chips containing "natural ingredients" because she did not purchase those varieties); *Rawa v. Monsanto Co.*, 2017 WL 3392090, at *5 (E.D. Mo. Aug. 7, 2017) (dismissing claim for lack of standing because the plaintiff did not purchase the product at issue).

C. Plaintiffs' Attempt To Regulate BPO Drug Safety and Warnings Is Expressly and Impliedly Preempted.

The BPO Products are acne drugs that contain benzoyl peroxide. (Compl. ¶ 1.) They are regulated by the Acne Monograph and therefore are subject to "requirement[s] under [the FDCA]" for purposes of 21 U.S.C. § 379r(a). *See* 21 C.F.R. § 333.310 (listing active

ingredients). Section 379r(a) provides that states may not establish "any requirement . . . (1) that relates to the regulation of a [nonprescription drug]; and (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under [the FDCA] . . . ." 21 U.S.C. § 379r(a); *Stephens v. Target Corp*., 22-CV-1576 (PJS/DTS), 2023 WL 6218060, at *3 (D. Minn. Sep. 25, 2023). Moreover, "any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug" shall be deemed a state "requirement" that satisfies § 379r(a)(1). *Id.* § 379r(c)(2). Therefore, "state law cannot prohibit a statement on an OTC drug label that a monograph expressly authorizes, ***or require a warning or other statement that the applicable monograph does not require***." *Stephens*, 2023 WL 6218060, at *4 (emphasis added).

All of Plaintiffs' claims are premised on the theory that BPO Products contain unsafe levels of benzene and Target should be required to provide a warning about benzene. (Compl., ¶¶ 10, 11, 49, 67, 69, 94-96, 119-120, 131.) Plaintiffs' claims are expressly preempted because they demand divergence from the Acne Monograph, which does not impose or allow any warning language sought by Plaintiffs. 21 U.S.C. § 379r(a); 21 U.S.C. § 352(ee); 21 C.F.R. §§ 333.350(b), 333.350(c)(4), 333.350(d)(2). The Acne Monograph specifies "the drugs that may be sold over the counter within that category, and then sets out dosage and labeling requirements for each drug, including the precise language that must be used to describe each drug's indications and the precise warnings that must accompany each drug." *Stephens*, 2023 WL 6218060, at *1. Any deviation from the

prescribed indications, warnings, or directions would render the BPO Products misbranded. *See* Classification of Benzoyl Peroxide as Safe and Effective and Revision of Labeling to Drug Facts Format; Topical Acne Drug Products for Over-The-Counter Human Use; Final Rule, 75 FR 9767-01, 9772; 21 C.F.R. § 333.350(c)(4), (d)(2).

Nor can BPO Products legally list benzene, a possible contaminant, in the BPO Products' ingredients list. Active and inactive ingredients in an OTC drug must be listed on its label in alphabetical order. 21 C.F.R. §§ 201.66(c)(8); 201.66(d)(6). Active and inactive ingredients are defined as "components" that are "intended for use in the manufacture of a drug product . . ." 21 C.F.R. § 314.13(b) (defining "active ingredient," "inactive ingredient," and "component). Benzene is not an active or inactive ingredient, as, being a contaminant, benzene is not "intended for use in the manufacture of a drug product." *Id.* § 314.13(b); Compl. ¶¶ 6, 8, 10, 35; *see also* Compl. ¶ 137 ("Defendant did not list benzene as an ingredient or contaminant anywhere on the Products or advertising."). The Complaint thus impermissibly seeks to impose a requirement "that is . . . not identical with" the FDCA. *See* § 379r(a)(2).

All of Plaintiffs' claims are based on Target's failure to communicate information that would render the BPO Products misbranded and are therefore preempted. *See, e.g.*, *Anglin v. Edgewell Pers. Care Co*., 2018 WL 6434424, at *11 (E.D. Mo. Dec. 7, 2018) (dismissing claims where plaintiffs asked the court to impose changes or deviations to the testing requirement set out in the OTC Final Rule); *Brinkley v. Pfizer, Inc*., 772 F.3d 1133, 1139 (8th Cir. 2014) (finding design defect and implied warranty claims were preempted

by the FDCA and affirming the lower court's dismissal pursuant to a motion for judgment on the pleadings); *Moretti v. Mut. Pharm. Co*., 518 Fed. App'x 486, 487 (8th Cir. 2013) (affirming district court's grant of judgment on the pleadings on the basis of FDA preemption); *Ideus v. Teva Pharm. USA, Inc*., 2017 WL 6389630, at *2 (D. Neb. Dec. 12, 2017) (holding dismissal is nonetheless appropriate under Rule 12(b)(6) if the facts alleged in the complaint do not plausibly give rise to a claim that is not preempted); *Dougherty v. Source Nats., Inc*., 148 F. Supp. 3d 831, 835-36 (E.D. Mo. 2015) (granting motion to dismiss in labeling case based on FDCA preemption).

Plaintiffs cannot avoid Congress's preemptive intent by arguing they seek to impose "parallel" state law duties. *See Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 353 (2001) ("any violation of the FDCA" will not constitute a "parallel claim"; dismissing as preempted fraud claims that existed "solely by virtue of the FDCA disclosure requirements"). Private litigants may not bring a state law claim that is in substance, even if not in form, a claim for violating the FDCA. *Id.* at 349 n.4, 353. Plaintiffs cite FDCA-imposed general standards for product testing, quality, or recalls alleging Target should have done something different to make the BPO Products safe. But any attempt to ground a state-law duty to warn, reformulate, or recall in purported violations of the FDCA is preempted. *See Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 488–90 (2013) (holding "state-law design-defect claims . . . that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling.").

It is FDA's job to enforce the FDCA and to evaluate whether the BPO Products are safe. *See* 21 U.S.C. § 337(a). In leveling claims about contamination and *risk of contamination* indiscriminately against BPO Products, regardless of whether they contain benzene, who made or distributed them, when they were manufactured, or how they were handled, Plaintiffs attempt to subvert FDA's determination that OTC BPO acne drugs that conform to the Acne Monograph are generally recognized as safe. Plaintiffs' request for relief is therefore preempted. *See McMullen v. Medtronic, Inc.*, 2004 WL 2538642, at *9 (S.D. Ind. Sept. 16, 2004), *aff'd*, 421 F.3d 482 (7th Cir. 2005) (claim of continuing duty to warn preempted because argument couched as defendant's failure to adhere to FDA warning requirements was actually argument the FDA-imposed warnings were inadequate and sought to impose a state-law standard of care); *Gomez v. St. Jude Med. Diag. Div. Inc.*, 442 F.3d 919, 932 (5th Cir. 2006) ("[Plaintiffs'] state-law claims related to [the manufacturer's] alleged failure to provide information obtained after the FDA approved the [device] risk the same interference with the federal regulatory scheme as her other claims and are preempted").

Finding that Plaintiffs' claims are preempted would be consistent with Chief Judge Schiltz's analysis in *Stephens v. Target Corp*., although he reached a different result in that case. No. 22-CV-1576 (PJS/DTS), 2023 WL 6218060, at *4 (D. Minn. Sept. 25, 2023). In *Stephens*, Judge Schiltz declined to apply preemption where the product at issue *affirmatively included* "non-drowsy" or "daytime" in product labeling. Chief Judge Schiltz found there was a "difference between state-law claims seeking to require that disclosure

language be added to a [] label when federal regulations did not explicitly require it and *state-law claims seeking only to stop defendants from voluntarily adding deceptive language* to the federally permitted labels." *Id.* at *5 (quotations omitted) (emphasis added). That distinction is critical here. In this case, Plaintiffs' claims are all grounded in the theory that Target should have added label language mentioning benzene as a contaminant or possible contaminant (*See, e.g.*, Compl. ¶¶ 10, 11, 49, 67, 69, 94-96, 119-120, 131.) Such a requirement would be a classic prohibition under preemption because "state law cannot… require a warning or other statement that the applicable monograph does not require." *Id.* at *4.

D. Plaintiffs' Claims Should Be Dismissed under the Primary Jurisdiction Doctrine.

Even if the Court does not conclude Plaintiffs' claims are preempted, they should still be dismissed because the questions presented in this case are within the primary jurisdiction of FDA. Primary jurisdiction permits courts to dismiss an otherwise cognizable claim when, as here, it is within the "special competence" of a regulatory agency that should resolve it in the first instance. *Qwest Corporation v. City of Inver Grove Heights*, No. 10-cv-2372 (ADM/SRN), 2010 WL 5139211, at *7 (D. Minn. Dec. 10, 2010). The Eighth Circuit has a flexible test for determining whether to apply the doctrine of primary jurisdiction. *Access Telecommunications v. Southwestern Bell*, 137 F.3d 605, 608 (8th Cir. 1998). Courts apply the doctrine of primary jurisdiction "to obtain the benefit of an

agency's expertise and experience" and to "promote uniformity and consistency within the particular field of regulation." *Id.*

Plaintiffs' allegations challenge the safety of an entire category of acne drugs and call for their removal from the market. Whether BPO Products are safe for use under the conditions prescribed in the Acne Monograph or should be removed from the market are issues squarely within FDA's field of expertise and firmly committed to FDA's discretion. 21 C.F.R. § 333.301 *et al*. Here, Plaintiffs have filed their complaint based on Valisure's Citizen Petition alleging "newly discovered variable nature of BPO formulation instability and variable rates of formation of benzene." (Ex. 1, (Citizen Petition) at 28). There is a real risk that courts and juries could reach inconsistent rulings on whether the OTC BPO acne drug claims are permissible under state law based on the "new" information in the Citizen Petition asking for these products to be found unsafe and removed from the market. Further, as already noted, Valisure has already initiated FDA's review of the safety of topical OTC BPO acne drugs under FDA's Citizen Petition process (Compl., ¶ 4), the process expressly designed by Congress for the re-evaluation of OTC drug monographs when new information comes to light. Whether under a preemption or primary jurisdiction theory, dismissal with prejudice or a stay of the action is required.

E. Plaintiffs' Claims Fail To Satisfy Rule 9(b).

Plaintiffs' claims sound in fraud and thus must be alleged with particularity under Rule 9(b). *Nunez v. Best Buy Co., Inc.*, 315 F.R.D. 245, 248 (D. Minn. 2016) (Rule 9(b) "applies to all claims premised on fraud, including 'claims of false advertising, deceptive

trade practices, unlawful trade practices, and consumer fraud.'" (quotations omitted)); *see also Ascente Bus. Consulting, LLC v. DR myCommerce*, 9 F.4th 839, 844 (8th Cir. 2021) ("Minnesota law treats even the fraud-adjacent claims like fraud."). To satisfy Rule 9(b), "[t]he complaint must plead the 'who, what, where, when, and how' of the alleged fraud." *Drobnak v. Andersen Corp.*, 561 F.3d 778, 783 (8th Cir. 2009) (quoting *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 556 (8th Cir. 2006)). "[C]onclusory allegations that a defendant's conduct was fraudulent and deceptive are not sufficient to satisfy the rule." *Schaller Tel. Co. v. Golden Sky Sys., Inc.*, 298 F.3d 736, 746 (8th Cir. 2002).

Plaintiffs have not satisfied these requirements. The alleged "deception" here must be predicated on the presence of benzene in Plaintiffs' BPO Products, allegedly rendering them unsafe. Plaintiffs' failure to allege any facts that their BPO Products actually contained benzene means they have not alleged how they were deceived. They also fail to allege any degradation or exposure of their PBO Products, including the normal shipping and handling of the BPO Products in 2022, or even the conditions in which they stored or used their BPO Products. There is no support that their BPO Products contained or degraded to contain benzene, and accordingly Plaintiffs have failed to allege any particularized facts showing the "how" of any alleged fraud.

F. Plaintiffs' Request For Equitable Relief Under Their Unjust Enrichment Claim Fails Because They Allege Adequate Legal Remedies.

The Eighth Circuit has long recognized "[t]hat a suit in equity does not lie where there is a plain adequate and complete remedy at law." *Pharm. Rsch. & Mfrs. of Am. v. Williams,* 64 F.4th 932, 942 (8th Cir. 2023). Here, as in *Stephens v. Target Corp*., No. 22-CV-1576 (PJS/DTS), 2023 WL 6218060, at *8 (D. Minn. Sept. 25, 2023), Plaintiffs have failed to plead, even in the alternative, that they lack an adequate remedy at law. In reaching that decision, Judge Schiltz relied on cases from across the country that similarly denied unjust enrichment claims predicated on consumer protection claims. *See, e.g*., *Collins v. eMachines, Inc*., 202 Cal. App. 4th 249, 134 Cal. Rptr 3d 588, 596–97 (2011) (affirming dismissal of unjust-enrichment claim based on conclusion that plaintiff's consumer-protection claims provided adequate legal remedy); *Mannos v. Moss*, 143 Idaho 927, 155 P.3d 1166, 1173 (2007) (holding unjust-enrichment claim was not viable where plaintiff had "the ability to pursue other legal remedies, including a claim for fraud"); *Shaw v. Hyatt Int'l Corp*., 461 F.3d 899, 902 (7th Cir. 2006) (affirming dismissal of unjust-enrichment claim pleaded alongside consumer-protection claim and premised on breach of contractual promise (citing *Guinn v. Hoskins Chevrolet*, 361 Ill. App. 3d 575, 296 Ill. Dec. 930, 836 N.E. 2d 681, 704 (2005))).

Plaintiffs have not shown and cannot show that an adequate legal remedy is unavailable. Plaintiffs' legal and equitable claims are all based on the same factual predicates, alleging they purchased BPO Products they would not have bought but for

Target's statements and misrepresentations. Plaintiffs further confirm the "damages sought [from these purchases] are ascertainable." (Compl. ¶ 101.) Plaintiff admits they have an adequate remedy at law, thereby precluding them from obtaining any equitable relief.

G. Plaintiffs Have No Cognizable Basis For Injunctive Relief.

A plaintiff must demonstrate constitutional standing separately for each form of relief requested. *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC) Inc.*, 528 U.S. 167, 185 (2000). To seek injunctive relief, Plaintiffs must show "actual and imminent" or "certainly impending" injury that is "not conjectural or hypothetical." *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009); *see also Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 422 (2013) (holding "respondents lack Article III standing because they cannot demonstrate that the future injury they purportedly fear is certainly impending").

The Eighth Circuit has dismissed requests for injunctive relief when, as here, the allegations do not show the plaintiff is likely to be harmed in the future. *Missouri v. Biden*, 52 F.4th 362, 369 (8th Cir. 2022), *cert. denied*, 144 S. Ct. 278 (2023) ("We agree with the district court that the 'Interim SC-GHG estimates, alone, do not injure Plaintiffs. . . . The injury that Plaintiffs fear is from hypothetical future regulation possibly derived from these Estimates.'"); *In re Pawn Am. Consumer Data Breach Litig.*, No. 21-CV-2554 (PJS/JFD), 2022 WL 3159874, at *3 (D. Minn. Aug. 8, 2022) ("Nothing alleged in the complaint indicates that a second breach of Pawn America's computer system is imminent."). Plaintiffs make no allegation they might be harmed in the future by Target's conduct. Indeed, nothing in Plaintiffs' Amended Complaint implies in any way that they would

attempt to purchase BPO Products again, even if Target changed the labeling language. Instead, Plaintiffs allege all BPO Products are unsafe because of the "unacceptably high levels of benzene." (Compl., ¶ 7.) Thus, it is implausible that Plaintiffs, operating under this (mistaken) belief, would ever purchase the BPO Products again, foreclosing any risk of future harm.

Because Plaintiffs have not shown they are likely to be deceived again, they have no basis for injunctive relief. *See, e.g.*, *May v. Makita U.S.A., Inc*., 2023 WL 3619354, at *10 (E.D. Mo. May 24, 2023) ("[I]n this case, it just so happens plaintiff pleads no facts showing there is the possibility of him being fooled twice. He was deceived once, he now knows of defendant's tricks, and he has pled nothing to suggest he will be deceived 'twice' again."); *Frankle v. Best Buy Stores, L.P*., 609 F. Supp. 2d 841, 849 (D. Minn. April 22, 2009) (holding the plaintiff did not sufficiently plead Article III standing because the plaintiff would not benefit from a preliminary injunction in that the plaintiff was already aware of the defendant's alleged failures); *see also Darisee v. Nest Labs, Inc*., 2016 WL 4385849, at *4 (N.D. Cal. Aug. 15, 2016) (holding that plaintiff lacked standing for injunctive relief because he was "not going to trust what [defendant company] says now," and thus faced no threat of future injury).

IV. CONCLUSION

For the foregoing reasons, the Court should grant Defendant's Motion to Dismiss and dismiss this case with prejudice in its entirety.

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